UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF
PREVENTION,
PESTICIDES
AND TOXIC
SUBSTANCES

August 9, 2010

MEMORANDUM

Subject: Efficacy Review for EPA Reg. No. 70271-13, Pure Bright Germicidal Ultra Bleach; DP Barcode: 377201

From: Tajah Blackburn, PhD, Microbiologist
Efficacy Evaluation Team
Product Science Branch
Antimicrobials Division (7510P)

8/9/10

To: Wanda Henson, PM 32
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Applicant: KIK International, Inc
33 Macintosh Blvd.
Concord, Ontario L4K4L5

Formulation from the Label:

Active Ingredient(s)	% by wt.
Sodium Hypochlorite	6.0%
Other Ingredients	94.0%
Total	100.0%

I BACKGROUND

The product, Pure Bright Germicidal Ultra Bleach (EPA Reg. No. 70271-13), is an EPA-approved disinfectant (bactericide, fungicide, virucide), sanitizer, mildewcide, and deodorizer for use on hard, non-porous surfaces in household, commercial, institutional, food service, animal care, and hospital or medical environments. The applicant requested to amend the registration of this product to add claims regarding use of the product as a disinfectant against additional microorganisms, as a non-food contact sanitizer, and as a laundry sanitizer. Studies were conducted at ATS Labs, located at 1285 Corporate Center Drive, Suite 110, in Eagan, MN 55121.

This data package contained a letter from the applicant's representative (dated April 13, 2010), EPA Form 8570-1 (Application for Pesticide), EPA Form 8570-27 (Formulator's Exemption Statement), EPA Form 8570-34 (Certification with Respect to Citation of Data), EPA Form 8570-35 (Data Matrix), eight studies (MRID 480623-01 through 480623-08), Statements of No Data Confidentiality Claims for all eight studies, and the proposed label.

II USE DIRECTIONS

The product is designed for disinfecting and sanitizing hard, non-porous surfaces. The product may be used to treat hard, non-porous surfaces such as appliances, bathtubs, cages, counter tops, cutting boards (hard, non-porous plastic), faucets, floors, furniture, garbage disposals, kennels, mops, shower curtains, shower walls, showers, sinks, toys, trash bins, trash cans, walls, and work surfaces. The proposed label indicates that the product may be used on hard, non-porous surfaces including: glass, glazed ceramic tile, glazed porcelain, linoleum, painted woodwork, and vinyl. Directions on the proposed label provide the following information regarding preparation and use of the product:

> As a disinfectant against Human immunodeficiency virus type 1 (HIV-1), Hepatitis B virus, and Hepatitis C virus in the presence of 5% blood serum: Use 1 ½ cup of the product per 1 gallon of water (5,000 ppm available chlorine). Leave surfaces wet for 5 minutes. Drain and let air dry.
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> As a disinfectant against *Clostridium difficile* spores: Clean surfaces by removing gross filth. Apply a 1:6 use solution of the product (~10,000 ppm available chlorine) to surfaces. Let stand for 10 minutes. Rinse and air dry.
>
> As a disinfectant against other label-specified microorganisms: Use ¾ cup of the product per 1 gallon of water (a 1:21 dilution). Wash, rinse, or wipe surfaces. Then, apply use solution. Let stand for 5 minutes. Rinse thoroughly and air dry.
>
> As a sanitizer: Use 1 tablespoon of the product per 1 gallon of water (a 1:257 dilution). Wash, rinse, or wipe surfaces. Then, apply use solution. Let stand for 5 minutes. Air dry.
>
> As a laundry sanitizer: Add 1¼ cup of the product per laundry load (a 1:205 dilution) for a conventional washing machine (16 gallon capacity). Add 2/3 cup of

the product per laundry load for an automatic front loading washing machine (8 gallon capacity). Add to pre-soak, wash water. If clothes are in the machine, dilute the product with 1 quart of wash water before adding.

III AGENCY STANDARDS FOR PROPOSED CLAIMS

Disinfectants for Use on Hard Surfaces in Hospital or Medical Environments (Additional Bacteria)

Effectiveness of disinfectants against specific bacteria other than those named in the AOAC Use-Dilution Method, AOAC Germicidal Spray Products as Disinfectants Method, AOAC Fungicidal Test, and AOAC Tuberculocidal Activity Method, must be determined by either the AOAC Use-Dilution Method or the AOAC Germicidal Spray Products as Disinfectants Method. Ten carriers must be tested against each specific microorganism with each of 2 product samples, representing 2 different product lots. To support products labeled as "disinfectants" for specific bacteria (other than those bacteria named in the above test methods), killing of the specific microorganism on all carriers is required.

Virucides

The effectiveness of virucides against specific viruses must be supported by efficacy data that simulates, to the extent possible in the laboratory, the conditions under which the product is intended to be used. Carrier methods that are modifications of either the AOAC Use-Dilution Method (for liquid disinfectants) or the AOAC Germicidal Spray Products as Disinfectants Method (for spray disinfectants) must be used. To simulate in-use conditions, the specific virus to be treated must be inoculated onto hard surfaces, allowed to dry, and then treated with the product according to the directions for use on the product label. One surface for each of 2 different product lots of disinfectant must be tested against a recoverable virus titer of at least 10^4 from the test surface for a specified exposure period at room temperature. Then, the virus must be assayed by an appropriate virological technique, using a minimum of four determinations per each dilution assayed. Separate studies are required for each virus. The calculated viral titers must be reported with the test results. For the data to be considered acceptable, results must demonstrate complete inactivation of the virus at all dilutions. When cytotoxicity is evident, at least a 3-log reduction in titer must be demonstrated beyond the cytotoxic level.

Virucides – Novel Virus Protocol Standards

To ensure that a virus protocol has been adequately validated, data should be provided from at least 2 independent laboratories for each product tested (i.e., 2 product lots per laboratory).

Sporicidal Disinfectant against *Clostridium difficile*

The Agency has established interim guidance for the efficacy evaluation of antimicrobial products (e.g., dilutable products, ready-to-use products, spray products, towelettes) that are labeled for use to treat hard, non-porous surfaces in healthcare settings contaminated with spores of *Clostridium difficile*. The effectiveness of such a product must be substantiated by data derived from one of the following four test

methods: Most recent version (2006) of AOAC Method 966.04: AOAC Sporicidal Activity of Disinfectants Test, Method I for *Clostridium sporogenes*; AOAC Method 2008.05: Quantitative Three Step Method (Efficacy of Liquid Sporicides Against Spores of *Bacillus subtilis* on a Hard Nonporous Surface); ASTM E 2414-05: Standard Test Method for Quantitative Sporicidal Three Step Method (TSM) to Determine Efficacy of Liquids, Liquid Sprays, and Vapor or Gases on Contaminated Carrier Surfaces; or ASTM E 2197-02: Standard Quantitative Carrier Test Method to Evaluate the Bactericidal, Fungicidal, Mycobactericidal, and Sporicidal Potencies of Liquid Chemical Germicides. Modifications to each test method will be necessary to specifically accommodate spores of *Clostridium difficile*. Because *Clostridium difficile* is an obligate anaerobe, testing should ensure adequate incubation conditions for the recovery of viable spores. The following toxigenic strains of *Clostridium difficile* may be used for testing: ATCC 700792, ATCC 43598, or ATCC 43599. All products must carry a pre-cleaning step, thus no organic soil should be added to the spore inoculum. Results must show a minimum 6 log reduction of viable spores in 10 minutes or less. Control carrier counts must be greater than 10^6 spores/carrier.

Sanitizers (For Non-Food Contact Surfaces)

The effectiveness of sanitizers for non-food contact surfaces must be supported by data that show that the product will substantially reduce the numbers of test bacteria on a treated surface. The test surface(s) should represent the type(s) of surfaces recommended for treatment on the label, i.e., porous or non-porous. Products that are represented as "one-step sanitizers" should be tested with an appropriate organic soil load, such as 5 percent serum. Tests should be performed with each of 3 product samples, representing 3 different product lots, one of which is at least 60 days old against *Staphylococcus aureus* (ATCC 6538) and either *Klebsiella pneumoniae* (aberrant, ATCC 4352) or *Enterobacter aerogenes* (ATCC 13048 or 15038). Results must show a bacterial reduction of at least 99.9 percent over the parallel control within 5 minutes.

Laundry Sanitizer

The effectiveness of laundry sanitizers must be supported by data that show that the product will substantially reduce the numbers of test bacteria on fabric and in laundry water. Laundry additives may either be used as soaking treatments prior to laundering or as treatments added during laundry operations. The label must specify the type of use. Laundry additives may be recommended for household/coin-operated machine use or commercial-industrial-institutional use. The label must specify the type of use. There is a significant difference in the water to fabric ratio between these two uses, which may affect the efficacy of the product. Tests should be conducted using a simulated-use procedure such as Petrocci and Clarke's "Proposed Test Method for Antimicrobial Laundry Additives" or a simulated use study involving washing machines. Tests should be performed with each of 3 product samples, representing 3 different lots, one of which is at least 60 days old. Tests should be conducted against *Staphylococcus aureus* (ATCC 6538) and *Klebsiella pneumoniae* (ATCC 4352). Products labeled as being suitable for hospital use must also be tested against *Pseudomonas aeruginosa* (ATCC 15442). Each product lot must be tested with 3 fabrics swatches against each of the test organisms. The method employed must include subculturing of both the fabric and the laundry water. The laundry water to media volume ratio must not exceed 1:40. Testing

of a 0.5 mL sample of laundry water from the simulated washing device (or a 5 mL sample from the automatic washer) is recommended. Results from a quantitative bacteriological assay must be reported. Results must show a bacterial reduction of 99.9% over the control count for both fabric and laundry water for each organism tested. The label directions for use of laundry additives should specify the machine cycle in which the product is to be added, as well as water level, temperature, and treatment time. Compatibility of the treatment with other laundry additives should be determined in testing and addressed in labeling, when applicable. These Agency standards are presented in DIS/TSS-13, and do not apply to sodium-calcium hypochlorites, sodium-potassium dichloro-s-triazinetriones, or trichloro-s-triazinetrione.

Note: The water to fabric ratio in industrial laundering operations is about 5:1. Dosages may be based on pounds of fabric for industrial machines. The water to fabric ratio in household laundering operations is 1:10.

Supplemental Claims

An antimicrobial agent identified as a "one-step" disinfectant or as effective in the presence of organic soil must be tested for efficacy with an appropriate organic soil load, such as 5 percent serum.

IV COMMENTS ON THE SUBMITTED EFFICACY STUDIES

1. MRID 480623-01 "Standard Quantitative Disk Carrier Test Method," Test Organism: *Clostridium difficile* (spore form) (ATCC 700792), for Pure Bright Germicidal Ultra Bleach, by Becky Lien. Study conducted at ATS Labs. Study completion date – February 5, 2010. Project Number A08850.

This study was conducted against *Clostridium difficile* (spore form) (ATCC 700792). Three lots (Lot Nos. 09343MKIK, 09344MKIK, and 09292MKIK) of the product, Pure Bright Germicidal Ultra Bleach, were tested using the ATSM Standard Quantitative Disk Carrier Test Method (ASTM E2197). At least one of the product lots tested (i.e., Lot No. 09292MKIK) was at least 60 days old at the time of testing. Use solutions were prepared by adding 1.00 mL of the product and 4.2 to 4.8 mL of filter sterilized tap water (available chlorine titrated at 51,906-57,938 ppm). A culture of the challenge microorganism was prepared in accordance with ASTM method specifications. From stock, one 10 ml tube of BHI broth was incubated for ≥24 hours at 35-37°C under anaerobic conditions. Following incubation, 10µl aliquots of broth culture were transferred to 298 tubes containing 10 ml of BHI. The tubes were incubated for 10 days at 35-37°C under anaerobic conditions. Following incubation, the broth cultures were centrifuge concentrated at 3750 RPM for 20 minutes. The supernatant was removed and the pellet was resuspended in filter sterilized deionized water in a volume equal to the volume of the supernatant removed. The resuspended mixture was centrifuged concentrated at 3750 RPM for 20 minutes. The supernatant was removed and the pellet was resuspended in the same volume of filter sterilized deionized water used in the previous step. The resuspended mixture was centrifuge concentrated at 3750 for 20 minutes. The supernatant was removed and the pellet was resuspended in 23.5 ml of filter sterilized deionized water in order to target a concentration of 125X to achieve a minimum concentration of 2 $x10^8$ spores/ml. The product was not tested in the presence of a 5% organic soil load. Twenty (20) brushed stainless steel disk carriers (1 cm diameter, 0.7 mm thick) per product lot were inoculated with 25 µL of a 10-day old

culture of test organism. The carriers were dried in a vacuum desiccator for 2 hours at 21°C. Each carrier was transferred, inoculated side up, to a QCT vial, to which 125 µL of the use solution was added. The carriers remained exposed to the use solution for 10 minutes at 21°C. Following exposure, 9.9 mL of Letheen Broth with 1.0% sodium thiosulfate was added to each vial to neutralize. The contents of each vial were vortex mixed for 45-60 seconds. As necessary, carriers were scraped with a cell scraper (while flushing the carrier surface with neutralizer) to remove any remaining inoculum from the carrier surface. The contents of each vial were poured through an individual membrane filter. Each vial was rinsed with saline four times, with each rinse poured through the same membrane filter. Each membrane filter was plated on Brucella agar and incubated for 45.5 hours at 35-37°C. Following incubation, the subcultures were examined for the presence or absence of visible growth. Controls included those for initial suspension count, carrier population, purity, sterility, neutralization confirmation, and acid resistance (2 and 5 minutes).

Note: A protocol modification accompanying the study was reviewed.
Note: Protocol deviations/amendments reported in the study were reviewed.

2. MRID 480623-02 "AOAC Use-Dilution Method," Test Organism: Methicillin Resistant *Staphylococcus aureus* (ATCC 33592), for Pure Bright Germicidal Ultra Bleach, by Becky Lien. Study conducted at ATS Labs. Study completion date – February 11, 2010. Project Number A08845.

This study was conducted against Methicillin Resistant *Staphylococcus aureus* (ATCC 33592). Two lots (Lot Nos. 09343MKIK and 09344MKIK) of the product, Pure Bright Germicidal Ultra Bleach, were tested using the AOAC Use-Dilution Method as described in the AOAC Official Methods of Analysis, 15th Edition, 1990. Use solutions were prepared by adding 12.0 mL of the product and 255.6 mL of filter sterilized tap water (a ¾ cup + 1 gallon dilution; a 1:21 dilution). A culture of the challenge microorganism was prepared in accordance with the published AOAC methods. Use solutions were not tested in the presence of a 5% organic soil load. Ten (10) stainless steel penicylinder carriers per product lot were immersed for 15 minutes in a 48-54 hour old suspension of test organism, at a ratio of 1 carrier per 1.0 mL broth. The carriers were dried for 40 minutes at 35-37°C at 53% relative humidity. Each carrier was placed in 10.0 mL of the use solution for 5 minutes at 20.0°C. Following exposure, individual carriers were transferred to 10 mL of Letheen Broth with 0.2% sodium thiosulfate to neutralize. All subcultures were incubated for 46 hours at 35-37°C. Following incubation, the subcultures were examined for the presence or absence of visible growth. Controls included those for carrier population, purity, sterility, viability, neutralization confirmation, and antibiotic resistance.

Note: Antibiotic resistance of Methicillin Resistant *Staphylococcus aureus* (ATCC 33592) was verified on a representative culture. The laboratory performed a Kirby Bauer Susceptibility assay. *Staphylococcus aureus* (ATCC 25923) was the control organism. The measured zone of inhibition (i.e., 6 mm) confirmed antibiotic resistance of Methicillin Resistant *Staphylococcus aureus* (ATCC 33592) to oxacillin. See page 9 and Table 5 of the laboratory report.

3. MRID 480623-03 "Virucidal Efficacy of a Disinfectant for Use on Inanimate Environmental Surfaces, Virus: Influenza A (H1N1) virus," for Pure Bright Germicidal Ultra Bleach, by Kelleen Gutzmann. Study conducted at ATS Labs. Study completion date – March 24, 2010. Project Number A09076.

This study was conducted against Influenza A (H1N1) virus (Strain A/PR/8/34; ATCC VR-1469), using RMK cells (Rhesus monkey kidney cells; obtained from ViroMed Laboratories, Inc., Cell Culture Division; maintained in-house) as the host system. Two lots (Lot Nos. 09343MKIK and 09344MKIK) of the product, Pure Bright Germicidal Ultra Bleach, were tested according to ATS Labs Protocol No. DAC02112509.FLUA (copy provided). Use solutions were prepared by adding 1.00 mL of the product and 21.0 mL of filter sterilized tap water (a ¾ cup + 1 gallon dilution; a 1:22 dilution). The stock virus culture contained 1% fetal bovine serum as the organic soil load. Films of virus were prepared by spreading 0.2 mL of virus inoculum uniformly over the bottoms of separate sterile glass Petri dishes. The virus films were air-dried for 20 minutes at 20.0°C at 50% relative humidity. For each lot of product, separate dried virus films were exposed to 2.00 mL of the use solution for 5 minutes at 20.0°C. Following exposure, the plates were scraped with a cell scraper to re-suspend the contents. The virus-disinfectant mixtures were passed immediately through individual Sephadex columns, and diluted serially in Minimum Essential Medium with 1% heat-inactivated fetal bovine serum, 10 µg/mL gentamicin, 100 units/mL penicillin, and 2.5 µg/mL amphotericin B. RMK cells in multi-well culture dishes were inoculated in quadruplicate with 0.1 mL of the dilutions. The cultures were incubated at 36-38°C in a humidified atmosphere of 5-7% CO_2. The cultures were scored periodically for 7 days for the presence or absence of unspecified cytopathic effects, cytotoxicity, and viability. Controls included those for input virus titer, dried virus count, cytotoxicity, and neutralization. Viral and cytotoxicity titers were calculated by the method of Spearman Karber.

4. MRID 480623-04 "Virucidal Efficacy of a Disinfectant for Use on Inanimate Environmental Surfaces, Virus: Human Immunodeficiency virus type 1," for Pure Bright Germicidal Ultra Bleach, by Mary J. Miller. Study conducted at ATS Labs. Study completion date – March 24, 2010. Project Number A09073.

This study was conducted against Human immunodeficiency virus type 1 (Strain HTLV-III_B; obtained from Advanced Biotechnologies, Inc., Columbia, MD), using MT-2 cells (human T-cell leukemia cells; obtained through the AIDS Research and Reference Reagent Program, Division of AIDS, NIAID, NIH; maintained in-house) as the host system. Two lots (Lot Nos. 09343MKIK and 09344MKIK) of the product, Pure Bright Germicidal Ultra Bleach, were tested according to ATS Labs Protocol No. DAC02112509.HIV (copy provided). Use solutions were prepared by adding 9.0 mL of the product and 108.0 mL of filter sterilized tap water (available chlorine titrated at 4914-4916 ppm; a 1:13 dilution). The stock virus culture was adjusted to contain 5% fetal bovine serum as the organic soil load. Films of virus were prepared by spreading 0.2 mL of virus inoculum uniformly over the bottoms of separate sterile glass Petri dishes. The virus films were air-dried for 20 minutes at 25.0°C at 4.9% relative humidity. For each lot of product, separate dried virus films were exposed to 2.00 mL of the use solution for 5 minutes at 20.0°C. Following exposure, the plates were scraped with a cell scraper to re-suspend the contents. The virus-disinfectant mixtures were passed

immediately through individual Sephadex columns, and diluted serially in RPMI with 10% (v/v) heat-inactivated fetal bovine serum, 50 µg/mL gentamicin, and 2.0 mM L-glutamine. MT-2 cells in multi-well culture dishes were inoculated in quadruplicate with 0.2 mL of the dilutions. The cultures were incubated at 36-38°C in a humidified atmosphere of 5-7% CO_2. The cultures were scored periodically for 8 days for the presence or absence of unspecified cytopathic effects, cytotoxicity, and viability. Controls included those for input virus titer, dried virus count, cytotoxicity, and neutralization. Viral and cytotoxicity titers were calculated by the method of Spearman Karber.

Note: A protocol modification accompanying the study was reviewed.

5. MRID 480623-05 "Virucidal Efficacy of a Disinfectant for Use on Inanimate Environmental Surfaces Utilizing Duck Hepatitis B Virus as a Surrogate Virus for Human Hepatitis B Virus," for Pure Bright Germicidal Ultra Bleach, by Mary J. Miller. Study conducted at ATS Labs. Study completion date – March 8, 2010. Project Number A08881.

This study, under the direction of Study Director Mary J. Miller, was conducted against Duck hepatitis B virus (Strain 7/31/07; obtained from HepadnaVirus Testing, Inc., Palo Alto, CA), using primary duck hepatocytes (cultures prepared by Valley Research Institute personnel using 2-day old Pekin breed hatchling ducks received from Metzer Farms) as the host system. Two lots (Lot Nos. 09343MKIK and 09344MKIK) of the product, Pure Bright Germicidal Ultra Bleach, were tested according to ATS Labs Protocol No. DAC02112509.DHBV.1 (copy provided). Use solutions were prepared by adding 4.5 mL of the product and 53.0 mL of filter sterilized tap water, or the equivalent (available chlorine titrated at 4973-4995 ppm; a 1:12.7-1:13 dilution). The stock virus culture contained 100% duck serum as the organic soil load. Films of virus were prepared by spreading 0.2 mL of virus inoculum uniformly over the bottoms of separate sterile glass Petri dishes. The virus films were air-dried for 30 minutes at 20.0°C at 50% relative humidity. Two replicates per product lot were tested. For each lot of product, separate dried virus films were exposed to 2.00 mL of the use solution for 10 minutes at 20.0°C. Following exposure, each plate was scraped with a cell scraper to re-suspend the contents. The virus-disinfectant mixtures were immediately passed through individual Sephadex columns. Ten-fold serial dilutions were prepared, using Leibovitz L-15 medium with 0.1% glucose, 10 µM dexamethasone, 10 µg/mL insulin, 20 mM HEPES, 10 µg/mL gentamicin, and 100 units/mL penicillin. Primary duck hepatocytes in multi-well culture dishes were inoculated in quadruplicate with 1.0 mL of selected dilutions. The cultures were allowed to adsorb overnight at 36-38°C in a humidified atmosphere of 5-7% CO_2. Post-adsorption, the cultures were re-fed. The cultures were returned to incubation for 9 days at 36-38°C in a humidified atmosphere of 5-7% CO_2. Test medium was aspirated from each well and replaced with fresh medium, as necessary. On the final day of incubation, the cultures were scored microscopically for cytotoxicity. The cultures then were examined for the presence of infectious virus using an indirect immunofluorescence assay. Controls included those for input virus titer, dried virus count, cytotoxicity, and neutralization. Viral and cytotoxicity titers were calculated by the method of Spearman Karber.

Note: A protocol modification accompanying the study was reviewed.

MRID not assigned; included as part of MRID 480623-05. "Virucidal Efficacy of a Disinfectant for Use on Inanimate Environmental Surfaces Utilizing Duck Hepatitis B Virus as a Surrogate Virus for Human Hepatitis B Virus – Confirmatory Assay," for Pure Bright Germicidal Ultra Bleach, by Kelleen Gutzmann. Study conducted at ATS Labs. Study completion date – March 17, 2010. Project Number A08880.

This confirmatory study, under the direction of Study Director Kelleen Gutzmann, was conducted against Duck hepatitis B virus (Strain 7/31/07; obtained from HepadnaVirus Testing, Inc., Palo Alto, CA), using primary duck hepatocytes (cultures prepared by Valley Research Institute personnel using 2-day old Pekin breed hatchling ducks received from Metzer Farms) as the host system. One lot (Lot No. 09344MKIK) of the product, Pure Bright Germicidal Ultra Bleach, was tested according to ATS Labs Protocol No. DAC02112509.DHBV.2. A use solution was prepared by adding 4.5 mL of the product and 54.0 mL of filter sterilized tap water (available chlorine titrated at 4990 ppm; a 1:13 dilution). The stock virus culture contained 100% duck serum as the organic soil load. Films of virus were prepared by spreading 0.2 mL of virus inoculum uniformly over the bottoms of separate sterile glass Petri dishes. The virus films were air-dried for 30 minutes at 20.0°C at 50% relative humidity. Two replicates for the single product lot were tested. For the single product lot, separate dried virus films were exposed to 2.00 mL of the use solution for 10 minutes at 20.0°C. Following exposure, each plate was scraped with a cell scraper to re-suspend the contents. The virus-disinfectant mixtures were immediately passed through individual Sephadex columns. Ten-fold serial dilutions were prepared, using Leibovitz L-15 medium with 0.1% glucose, 10 µM dexamethasone, 10 µg/mL insulin, 20 mM HEPES, 10 µg/mL gentamicin, and 100 units/mL penicillin. Primary duck hepatocytes in multi-well culture dishes were inoculated in quadruplicate with 1.0 mL of selected dilutions. The cultures were allowed to adsorb overnight at 36-38°C in a humidified atmosphere of 5-7% CO_2. Post-adsorption, the cultures were re-fed. The cultures were returned to incubation for 9 days at 36-38°C in a humidified atmosphere of 5-7% CO_2. Test medium was aspirated from each well and replaced with fresh medium, as necessary. On the final day of incubation, the cultures were scored microscopically for cytotoxicity. The cultures then were examined for the presence of infectious virus using an indirect immunofluorescence assay. Controls included those for input virus titer, dried virus count, cytotoxicity, and neutralization. Viral and cytotoxicity titers were calculated by the method of Spearman Karber.

Note: A protocol modification accompanying the study was reviewed.

6. MRID 480623-06 "Virucidal Efficacy of a Disinfectant for Use on Inanimate Environmental Surfaces Utilizing Bovine Viral Diarrhea Virus as a Surrogate Virus for Human Hepatitis C Virus," for Pure Bright Germicidal Ultra Bleach, by Mary J. Miller. Study conducted at ATS Labs. Study completion date – March 24, 2010. Project Number A09074.

This study, under the direction of Study Director Mary J. Miller, was conducted against Bovine viral diarrhea virus (Strain Oregon C24v-genotype 1; obtained from the National Veterinary Services Laboratories, Ames IA), using BT cells (bovine turbinate cells; ATCC CRL-1390, propagated in-house) as the host system. Two lots (Lot Nos. 09343MKIK and 09344MKIK) of the product, Pure Bright Germicidal Ultra Bleach, were tested according to ATS Labs Protocol No. DAC02112509.BVD.1. Use solutions were

prepared by adding 9.0 mL of the product and 108.0 mL of filter sterilized tap water (available chlorine titrated at 4914-4916 ppm; a 1:13 dilution). The stock virus culture was adjusted to contain 1% horse serum as the organic soil load. Films of virus were prepared by spreading 0.2 mL of virus inoculum uniformly over the bottoms of separate sterile glass Petri dishes. The virus films were air-dried for 20 minutes at 20.0°C at 50% relative humidity. Two replicates per product lot were tested. For each lot of product, separate dried virus films were exposed to 2.00 mL of the use solution for 10 minutes at 20.0°C. Following exposure, each plate was scraped with a cell scraper to re-suspend the contents. The virus-disinfectant mixtures were immediately passed through individual Sephadex columns. A 0.2 mL aliquot of the virus was re-suspended in 2.0 mL of the use solution, which equals a 1:10 dilution. Ten-fold serial dilutions were prepared, using Minimum Essential Medium with 5% (v/v) non-heat inactivated horse serum, 10 µg/mL gentamicin, 100 units/mL penicillin, and 2.5 µg/mL amphotericin B. BT cells in multi-well culture dishes were inoculated in quadruplicate with 0.1 mL of selected dilutions. The cultures were incubated at 36-38°C in a humidified atmosphere of 5-7% CO_2. The cultures were microscopically scored periodically for 8 days for the presence or absence of cytopathic effects (i.e., rounded, dark, with a granular appearance), cytotoxicity, and viability. On the final day of incubation, a direct immunofluorescence assay was performed to verify the cytopathic effect reading. Controls included those for input virus titer, dried virus count, cytotoxicity, and neutralization. Viral and cytotoxicity titers were calculated by the method of Spearman Karber.

Note: A protocol modification accompanying the study was reviewed.

MRID not assigned; included as part of MRID 480623-06. "Virucidal Efficacy of a Disinfectant for Use on Inanimate Environmental Surfaces Utilizing Bovine Viral Diarrhea Virus as a Surrogate Virus for Human Hepatitis C Virus – Confirmatory Assay," for Pure Bright Germicidal Ultra Bleach, by Kelleen Gutzmann. Study conducted at ATS Labs. Study completion date – March 30, 2010. Project Number A09075.

This confirmatory study, under the direction of Study Director Kelleen Gutzmann, was conducted against Bovine viral diarrhea virus (Strain Oregon C24v-genotype 1; obtained from the National Veterinary Services Laboratories, Ames IA), using BT cells (bovine turbinate cells; ATCC CRL-1390; propagated in-house) as the host system. One lot (Lot No. 09344MKIK) of the product, Pure Bright Germicidal Ultra Bleach, was tested according to ATS Labs Protocol No. DAC02112509.BVD.2. A use solution was prepared by adding 9.2 mL of the product and 108.0 mL of filter sterilized tap water (available chlorine titrated at 4913 ppm; a 1:12.7 dilution). The stock virus culture contained 1% horse serum as the organic soil load. Films of virus were prepared by spreading 0.2 mL of virus inoculum uniformly over the bottoms of separate sterile glass Petri dishes. The virus films were air-dried for 20 minutes at 20.0°C at 50% relative humidity. Two replicates for the single product lot were tested. For the single product lot, separate dried virus films were exposed to 2.00 mL of the use solution for 10 minutes at 20.0°C. Following exposure, each plate was scraped with a cell scraper to re-suspend the contents. The virus-disinfectant mixtures were immediately passed through individual Sephadex columns. A 0.2 mL aliquot of the virus was re-suspended in 2.0 mL of the use solution, which equals a 1:10 dilution. Ten-fold serial dilutions were prepared, using Minimum Essential Medium with 5% (v/v) non-heat inactivated horse serum, 10 µg/mL gentamicin, 100 units/mL penicillin, and 2.5 µg/mL amphotericin B. BT cells in multi-well culture dishes were inoculated in quadruplicate with 0.1 mL of selected

dilutions. The cultures were incubated at 36-38°C in a humidified atmosphere of 5-7% CO_2. The cultures were microscopically scored periodically for 7 days for the presence or absence of cytopathic effects (i.e., rounded, dark, with a granular appearance), cytotoxicity, and viability. On the final day of incubation, a direct immunofluorescence assay was performed to verify the cytopathic effect reading. Controls included those for input virus titer, dried virus count, cytotoxicity, and neutralization. Viral and cytotoxicity titers were calculated by the method of Spearman Karber.

Note: A protocol modification accompanying the study was reviewed.

7. MRID 480623-07 "Standard Test Method for Efficacy of Sanitizers Recommended for Inanimate Non-Food Contact Surfaces," Test Organisms: *Staphylococcus aureus* (ATCC 6538) and *Enterobacter aerogenes* (ATCC 13048), for Pure Bright Germicidal Ultra Bleach, by Becky Lien. Study conducted at ATS Labs. Study completion date – February 25, 2010. Project Number A09029.

This study was conducted against *Staphylococcus aureus* (ATCC 6538) and *Enterobacter aerogenes* (ATCC 13048). Three lots (Lot Nos. 09342M, 10034M, and 10035M) of the product, Pure Bright Germicidal Ultra Bleach, were tested. The laboratory report referenced the Sanitizer Test from DIS/TSS-10 and the Standard Test Method for Efficacy of Sanitizers Recommended for Inanimate Non-Food Contact Surfaces (ASTM E1153). At least one of the product lots tested (i.e., Lot No. 09342M) was at least 60 days old at the time of testing. Use solutions were prepared by adding 1.00 mL of the product and 256 mL of filter sterilized tap water (a 1 tablespoon + 1 gallon dilution; a 1:257 dilution). Use solutions were not tested in the presence of a 5% organic soil load. Five sterile glass carriers (1 inch x 1 inch) per product lot per microorganism were inoculated with 10.0 µL of a 48±4-hour old suspension of test organism (which differs from the 18-24 hour old suspension specified in DIS/TSS-10). The inoculum was spread to within 1/8 inch of the edges of each carrier. The carriers were dried for 20 minutes at 36.0°C at 40-42% relative humidity (which differs from the 40-minute drying time specified in DIS/TSS-10). Each carrier was transferred to a sterile jar and treated with 5.0 mL of the use solution for 5 minutes at 21°C. Following exposure, each carrier was treated with 20.0 mL of Letheen Broth with 1.0% sodium thiosulfate. The vessels were rotated vigorously on an even plane for ~50 rotations to suspend the surviving organisms. Within 30 minutes of the addition of the neutralizer, 1.00 mL aliquots of the 10^0 and 10^{-1} dilutions were plated in duplicate on tryptic soy agar with 5% sheep's blood. *Staphylococcus aureus* cultures were incubated for 46.5 hours at 35-37°C. *Enterobacter aerogenes* cultures were incubated for 46.5 hours at 25-30°C. Following incubation, the subcultures were visually enumerated. Controls included those for inoculum count, carrier quantitation, purity, sterility, and neutralization confirmation.

8. MRID 480623-08 "Standard Test Method for the Evaluation of Laundry Sanitizers," Test Organisms: *Staphylococcus aureus* (ATCC 6538) and *Klebsiella pneumoniae* (ATCC 4352), for Pure Bright Germicidal Ultra Bleach, by Becky Lien. Study conducted at ATS Labs. Study completion date – March 15, 2010. Project Number A09052.

This study was conducted against *Staphylococcus aureus* (ATCC 6538) and *Klebsiella pneumoniae* (ATCC 4352). Three lots (Lot Nos. 09342M, 10034M, and 10035M) of the product, Pure Bright Germicidal Ultra Bleach, were tested using ATS Protocol No. DAC02020310.LSAN (copy provided). The laboratory report referenced Petrocci and Clarke's "Proposed Test Method for Antimicrobial Laundry Additives." At least one of the product lots tested (i.e., Lot No. 09342M) was at least 60 days old at the time of testing. Use solutions of the product were prepared by adding 3.00 mL of the product and 615 mL of filter sterilized tap water (a 1¼ cup +16 gallon dilution; a ~1:205 dilution). Fetal bovine serum was added to each inoculum to achieve a 5% organic soil load. Sterile bottles were filled with 150.0 g of the prepared use solution and equilibrated to 20°C. The carriers for testing performed on September 18, 2009 were prepared by boiling 778 grams of plain cotton weave fabric (approximately 80 x 80 threads/inch) in a solution of 4.0 grams of Na_2CO_3, 4.0 grams of Triton X-100, and 8 liters of deionized water for 60 minutes. The carriers for testing performed on February 4, 2010 were prepared by boiling 597 grams of plain cotton weave fabric (approximately 80 x 80 threads/inch) in a solution of 3.0 grams of Na_2CO_3, 3.0 grams of Triton X-100, and 6 liters of deionized water for 60 minutes. The fabric then was rinsed in boiling water for 5-6 minutes and then rinsed in cold water for 5 minutes. During the rinsing procedure, the fabric was mixed in the water to help remove the wetting agent. After air-drying, the fabric was cut into 5 cm (~2 inch) wide strips weighing 15±1 grams. Each fabric strip was wrapped around a stainless steel spindle between 12 and 13 times. The fabric wrapped spindles were autoclave sterilized. Swatches (1 inch by 1.5 inch) were also cut from the remaining fabric. The fabric wrapped spindles and swatches were steam sterilized, allowed to cool, and held at room temperature until use. Three swatches per product lot per test organism were inoculated with 30 µL of the prepared organism culture, and dried in an incubator for 10 minutes at 35-37°C. After drying, the swatches were each inserted between the 6^{th} and 7^{th} lap of a wrapped spindle. Each spindle contained three dried, contaminated swatches. The spindles were placed in the sterile bottles containing the use solution and subjected to a simulated tumble-wash at 45-60 RPM for 10 minutes at 20°C. Following the simulated wash, a 1.00 mL aliquot of the wash water was transferred to a vessel containing 9.0 mL of Letheen Broth with 1.0% sodium thiosulfate to neutralize. Each fabric swatch was transferred to 10 mL of Letheen Broth with 1.0% sodium thiosulfate to neutralize. The fabric swatches were then vortex mixed for at least 10 seconds to extract fabric-bound microorganisms. A 1.00 mL aliquot of the neutralizing subculture medium was transferred to 9 mL of sterile diluent; representing the 10^{-1} dilution. Ten-fold serial dilutions were continued through the 10^{-4} dilution. Each dilution was plated using 1.00 mL of the 10^{0} to 10^{-4} dilutions in duplicate on tryptic soy agar with 5% sheep's blood. All subcultures were incubated for 46.25 hours at 35-37°C. Following incubation, standard plate count procedures were used to determine the average colony forming units per carrier (CFU/carrier) and per milliliter of wash water (CFU/mL). Controls included those for initial suspension count, population count, purity, sterility, viability, and neutralization confirmation.

Note: Adding a ca. 15-gram cloth strip to 150 mL of product use solution yields a 1:10 w/v ratio of simulated laundry to wash water, the appropriate ratio for household laundry additive testing.

Note: Protocol deviations/amendments reported in the study were reviewed.

V RESULTS

MRID Number	Organism	Lot No.	Total No. Surviving (CFU/carrier)	Parallel Control (CFU/carrier)	Percent Reduction
480623-07	*Staphylococcus aureus*	09342M	$<2.51 \times 10^1$	1.78×10^6	>99.9
		10034M	$<2.51 \times 10^1$	1.78×10^6	>99.9
		10035M	$<2.51 \times 10^1$	1.78×10^6	>99.9
	Enterobacter aerogenes	09342M	$<2.51 \times 10^1$	6.76×10^6	>99.9
		10034M	$<2.51 \times 10^1$	6.76×10^6	>99.9
		10035M	$<2.51 \times 10^1$	6.76×10^6	>99.9

MRID Number	Organism	No. Exhibiting Growth/ Total No. Tested		Carrier Population (CFU/ carrier)
		Lot No. 09343MKIK	Lot No. 09344MKIK	
480623-02	Methicillin Resistant *Staphylococcus aureus*	0/10	0/10	7.3×10^6

MRID No. 480623-01

Test Organism	Carrier#	Number of Survivors/Carrier	Log_{10} of Number Survivors/Carrier	Average Log_{10}	CFU/Carrier
Clostridium difficile	1	6.9×10^6	6.84	6.96	9.12×10^5
	2	9.7×10^6	6.99		
	3	1.13×10^7	7.053		

Lot Number #09343MKIK					
Test Organism	Carrier #	#Survivors/Test carrier (Log_{10})	Geometric Mean Test carriers (Avg Log_{10})	Geometric Mean Control Carriers (Average Log_{10})	Percent Reduction (Log_{10} reduction)
Clostridium difficile	1-6	<1 (<0.0)	<1 (<0.0)	9.12×10^6 (6.96)	>99.9999% (>6.9)
Lot Number #09344MKIK					
Clostridium difficile	1-6	<1 (<0.0)	<1 (<0.0)	9.12×10^6 (6.96)	>99.9999% (>6.9)
Lot Number #09292MKIK					
Clostridium difficile	1-6	<1 (<0.0)	<1 (<0.0)	9.12×10^6 (6.96)	>99.9999% (>6.9)

MRID Number	Organism	Results			Dried Virus Control
			Lot No. 09343MKIK	Lot No. 09344MKIK	
480623-03	Influenza A (H1N1) virus	10^{-1} to 10^{-8} dilutions	Complete inactivation	Complete inactivation	$10^{7.25}$ $TCID_{50}$/0.1 mL
		$TCID_{50}$/0.1 mL	$\leq 10^{0.5}$	$\leq 10^{0.5}$	
480623-04	Human immuno-deficiency virus type 1	10^{-1} dilution	Cytotoxicity	Cytotoxicity	$10^{5.5}$ $TCID_{50}$/0.2 mL
		10^{-2} to 10^{-7} dilutions	Complete inactivation	Complete inactivation	
		$TCID_{50}$/0.2 mL	$\leq 10^{1.5}$	$\leq 10^{1.5}$	
		Log reduction	≥ 4.0 $\log_{10}$	≥ 4.0 $\log_{10}$	
480623-05	Duck hepatitis B virus	10^{-2} to 10^{-4} dilutions	Complete inactivation	Complete inactivation	$10^{5.25}$ and $10^{5.0}$ $TCID_{50}$/1.0 mL
		$TCID_{50}$/1.0 mL	$\leq 10^{1.5}$	$\leq 10^{1.5}$	
MRID not assigned	Duck hepatitis B virus	10^{-2} to 10^{-4} dilutions	---	Complete inactivation	$10^{6.5}$ and $10^{6.25}$ $TCID_{50}$/1.0 mL
		$TCID_{50}$/1.0 mL	---	$\leq 10^{1.5}$	
480623-06	Bovine viral diarrhea virus	10^{-1} to 10^{-4} dilutions	Complete inactivation	Complete inactivation	$10^{4.5}$ $TCID_{50}$/0.1 mL
		$TCID_{50}$/0.1 mL	$\leq 10^{0.5}$	$\leq 10^{0.5}$	
MRID not assigned	Bovine viral diarrhea virus	10^{-1} to 10^{-4} dilutions	---	Complete inactivation	$10^{4.5}$ $TCID_{50}$/0.1 mL
		$TCID_{50}$/0.1 mL	---	$\leq 10^{0.5}$	

MRID/ Organism	Lot No.	Average No. Surviving (CFU/ swatch)	Microbes Initially Present (mean CFU/ swatch)	"Wash" Water Test Results (CFU/ mL)	"Wash" Water Control (CFU/ mL)	% Red.
Household Laundry Operations						
480623-08	*Staphylococcus aureus*					
	09342M	$<1 \times 10^1$	1.68×10^7	$<1 \times 10^1$	2.25×10^5	>99.9
	10034M	$<1 \times 10^1$		$<1 \times 10^1$		>99.9
	10035M	$<1 \times 10^1$		$<1 \times 10^1$		>99.9
480623-08	*Klebsiella pneumoniae*					
	09342M	$<1 \times 10^1$	1.24×10^7	$<1 \times 10^1$	1.10×10^6	>99.9
	10034M	$<1 \times 10^1$		$<1 \times 10^1$		>99.9
	10035M	$<1 \times 10^1$		$<1 \times 10^1$		>99.9

VI CONCLUSIONS

A. Conclusions Regarding Use of the Product as a Disinfectant Against *Clostridium difficile* Spores

1. The submitted efficacy data (MRID 480623-01) do not support the use of a 50,000 ppm available chlorine use solution of the product, Pure Bright Germicidal Ultra Bleach, as a disinfectant against *Clostridium difficile* on pre-cleaned surfaces for a 10-minute contact time. A 6-log reduction in viable spores was reported by the laboratory. The carrier test inoculum and test sample were increased in the test system (i.e. from 10µl to 50 µl of inoculum and from 50µl to 150 µl for the test sample) without prior Agency approval. At least one of the product lots tested was at least 60 days old at the time of testing. *Clostridium difficile* test spores showed resistance to acid for >2 minutes. Carrier population counts were at least $>10^6$ spores/carrier. Neutralization confirmation testing met the acceptance criterion of growth within 1 $\log_{10}$ of the numbers control. Purity controls were reported as pure. Sterility controls did not show growth.

B. Conclusions Regarding Use of the Product as a Disinfectant

1. The submitted efficacy data (MRID 480623-02) support the use of a 1:21 use solution of the product, Pure Bright Germicidal Ultra Bleach, as a disinfectant with bactericidal activity against Methicillin Resistant *Staphylococcus aureus* on pre-cleaned, hard, non-porous surfaces for a 5-minute contact time. Complete killing was observed in the subcultures of the required number of carriers tested against the required number of product lots. Neutralization confirmation testing showed positive growth of the microorganism. Purity controls were reported as pure. Viability controls were positive for growth. Sterility controls did not show growth.

2. The submitted efficacy data (MRID 480623-03) support the use of a 1:22 use solution of the product, Pure Bright Germicidal Ultra Bleach, as a disinfectant with virucidal activity against Influenza A (H1N1) virus on hard, non-porous surfaces in the presence of a 1% organic soil load for a 5-minute contact time. A recoverable virus titer of at least 10^4 was achieved. Cytotoxicity was not observed. Complete inactivation (no growth) was indicated in all dilutions tested.

3. The submitted efficacy data (MRID 480623-04) support the use of a 5,000 ppm available chlorine use solution of the product, Pure Bright Germicidal Ultra Bleach, as a disinfectant with virucidal activity against Human immunodeficiency virus type 1 on hard, non-porous surfaces in the presence of a 5% organic soil load for a 5-minute contact time. A recoverable virus titer of at least 10^4 was achieved. Cytotoxicity was observed in the 10^{-1} dilutions. Complete inactivation (no growth) was indicated in all higher dilutions tested. At least a 3-log reduction in titer was demonstrated beyond the cytotoxic level.

4. The submitted initial and confirmatory efficacy data (MRID 480623-05) support the use of a 5,000 ppm available chlorine use solution of the product, Pure Bright Germicidal Ultra Bleach, as a disinfectant with virucidal activity against Duck hepatitis B virus (as a surrogate virus for Human hepatitis B virus) on hard, non-porous surfaces in the presence of a 100% organic soil load for a 10-minute contact time. Recoverable virus titers of at least 10^4 were achieved. Cytotoxicity was not observed. Complete inactivation (no growth) was indicated in all dilutions tested. The initial and confirmatory

studies were performed at the same laboratory but under the direction of different study directors. Both the initial and confirmatory studies tested two replicates per product lot. The confirmatory study tested one product lot, not the standard two product lots.

5. The submitted initial and confirmatory efficacy data (MRID 480623-06) support the use of a 5,000 ppm available chlorine use solution of the product, Pure Bright Germicidal Ultra Bleach, as a disinfectant with virucidal activity against Bovine viral diarrhea virus (as a surrogate virus for Human hepatitis C virus) on hard, non-porous surfaces in the presence of a 1% organic soil load for a 10-minute contact time. Recoverable virus titers of at least 10^4 were achieved. Cytotoxicity was not observed. Complete inactivation (no growth) was indicated in all dilutions tested. The initial and confirmatory studies were performed at the same laboratory but under the direction of different study directors. Both the initial and confirmatory studies tested two replicates per product lot. The confirmatory study tested one product lot, not the standard two product lots.

C. Conclusions Regarding Use of the Product as a Sanitizer and Laundry Sanitizer

1. The submitted efficacy data partially support the use of a 1:257 use solution of the product, Pure Bright Germicidal Ultra Bleach, as a sanitizer against the following microorganisms on pre-cleaned, hard, non-porous, non-food contact surfaces for a 5-minute contact time:

Staphylococcus aureus	MRID 480623-07
Enterobacter aerogenes	MRID 480623-07

The registrant must explain the test protocol deviations: (1) culture was incubated for 48±4-hour which differs from the 18-24 hour old suspension requirement as specified in DIS/TSS-10; and (2) carriers were dried for 20 minutes instead of 40 minute-drying time as specified in DIS/TSS-10. Bacterial reductions of at least 99.9 percent over the parallel control were observed within 5 minutes. At least one of the product lots tested was at least 60 days old at the time of testing. The zero-time control count demonstrated an average of at least 7.5×10^5 surviving organisms, which is the criterion set forth in ASTM 1153. Neutralization confirmation testing met the acceptance criterion of growth within 1 $\log_{10}$ of the numbers control. Purity controls were reported as pure. Sterility controls did not show growth.

2. The submitted efficacy data support the use of a 1¼ cup per 16 gallon use solution of the product, Pure Bright Germicidal Ultra Bleach, to sanitize laundry during household laundry operations against the following microorganisms in the presence of a 5% organic soil load for a 10-minute contact time at 20°C (actually a ~1:205 dilution of the product):

Staphylococcus aureus	MRID 480623-08
Klebsiella pneumoniae	MRID 480623-08

A 99.9% reduction in population was observed in the subcultures for both the fabric swatches and the "wash" water tested against the required number of product lots. Three fabric swatches per product lot were tested. At least one of the product lots tested was at least 60 days old at the time of testing. Neutralization confirmation testing met the acceptance criterion of growth within 1 $\log_{10}$ of the numbers control. Purity controls

were reported as pure. Viability controls were positive for growth. Sterility controls did not show growth.

VII RECOMMENDATIONS

A. Recommendations Regarding Use of the Product as a Disinfectant Against *Clostridium difficile* Spores

1. The proposed label claims are unacceptable regarding the use of a 1:6 dilution (~10,000 ppm available chlorine) of the product, Pure Bright Germicidal Ultra Bleach as disinfectant against *Clostridium difficile* spores (ATCC 700792) on pre-cleaned, hard, non-porous surfaces for a 10-minute contact time. The protocol deviation, referenced in the Conclusion section, was not accepted by the Agency prior to data generation.

B. Recommendations Regarding Use of the Product as a Disinfectant

1. The proposed label claims that a ¾ cup product per gallon water use solution (a 1:21 dilution) of the product, Pure Bright Germicidal Ultra Bleach, is an effective disinfectant against the following microorganisms on pre-cleaned, hard, non porous surfaces for a 5-minute contact time:

Methicillin Resistant *Staphylococcus aureus* (ATCC 33592)
H1N1 Influenza A virus (ATCC VR-1469, Strain A/PR/8/34)

These claims are acceptable as they are supported by the submitted data.

2. The proposed label claims that a 5,000 ppm available chlorine use solution of the product, Pure Bright Germicidal Ultra Bleach, is an effective disinfectant against Human immunodeficiency virus type 1 on hard, non porous surfaces in the presence of 5% blood serum for a 5-minute contact time. This claim is acceptable as it is supported by the submitted data.

3. The proposed label claims that a 5,000 ppm available chlorine use solution of the product, Pure Bright Germicidal Ultra Bleach, is an effective disinfectant against the following viruses on hard, non-porous surfaces in the presence of 5% blood serum for a 5-minute contact time:

Hepatitis B virus (7/31/07 strain duck Hepatitis B)
Hepatitis C virus (Oregon C24v-genotype 1 Bovine Viral Diarrhea Virus)

Data provided do not support these claims. Efficacy against Hepatitis B virus was demonstrated in the presence of a 100% organic soil load for a 10-minute contact time. Efficacy against Hepatitis C virus was demonstrated in the presence of a 1% organic load for a 10-minute contact time.

C. Recommendations Regarding Use of the Product as a Sanitizer

1. The proposed label claims that a 1 tablespoon product per gallon water use solution (a 1:257 dilution) of the product, Pure Bright Germicidal Ultra Bleach, is an effective sanitizer against the following microorganisms on pre-cleaned, hard, non-porous, non-food contact surfaces for a 5-minute contact time:

Enterobacter aerogenes (ATCC 13048)
Staphylococcus aureus (ATCC 6538)

These claims are unacceptable until the appropriate rationale regarding protocol deviations is provided.

2. The proposed label claims that a 1¼ cup product per 16 gallon laundry load use solution (a 1:205 dilution) of the product, Pure Bright Germicidal Ultra Bleach, is an effective household laundry sanitizer against the following microorganisms on fabric surfaces:

Klebsiella pneumoniae (ATCC 4352)
Staphylococcus aureus (ATCC 6538)

These claims are acceptable as they are supported by the submitted data.

D. Miscellaneous Recommendations Regarding the Proposed Label

1. The directions for disinfecting/ sanitizing children's furniture and toys (on pages 9 and 14, respectively, of the proposed label) must be revised. The following step must be included in the directions: "Wash all surfaces thoroughly."

2. The following revisions to the proposed label are recommended:

- On page 2 of the proposed label under the "Precautionary Statements" section, change "Wash after handling." to read "Wash after handling and before eating, drinking, chewing gum, using tobacco, or using the toilet."

- On pages 3 and 5 of the proposed label, change "Klebsiella pheumoniae" to read "Klebsiella pneumoniae."

- On pages 3 and 5 of the proposed label, change "Methicillan Resistant" to read "Methicillin Resistant."

- On page 4 of the proposed label, the term "germs" should be removed in association of odor causing. The Agency has determined that germs include bacteria, viruses, and fungi. Germs are public health claims while odor-causing claims are non-public health claims.

- On page 4 of the proposed label, add the descriptor "from treated surfaces" to the claims "Helps prevent the spread of the cold and flu virus".

- On page 4 of the proposed label, remove the claims "powerful", "original

disinfectant", "and smart way to disinfect" as these claims are misleading and/or difficult to assess.

- On page 5 of the proposed label, change "Shigella Dyssenteriae" to read "Shigella dysenteriae."

- On page 5 of the proposed label (in the listing denoted with ***), change "Herpes simplex virus" to read "Herpes simplex virus type 2."

- On page 6 of the proposed label, the claims "purest white", "whitest white", and "more valuable" are unacceptable. The Agency has not determined how to measure/quantitate this claim.

- On page 9 of the proposed label, delete "mops" from the list of surfaces/objects. Mops have porous surfaces.

- On page 9 of the proposed label, change "enamel" to read "baked enamel." Enamel is a porous surface.

- On pages 9 and 14 of the proposed label, change "porcelain" to read "glazed porcelain." Porcelain is a porous surface.

- On page 10 of the proposed label under the "Disinfectant Use and Contact Time" section for treatment against HIV-1, HBV, and HCV, add the following (or similar) statement: "Heavily soiled surfaces must be pre-cleaned prior to disinfection."

- On page 14 of the proposed label under the "To Sanitize Hard Nonporous Surfaces" section, change "disinfecting solution" to read "sanitizing solution."

- All allergen claims must be qualified as non-living or include the non-living description before the term "allergen".

- In all lists of microorganisms, capitalization should be consistent (i.e., the genus should be capitalized and the species should be in lower case).

3. The letter from the applicant's representative to EPA (dated April 13, 2010) states – pages 2 and 3 – that use rates have been rounded so that they are easier to use. This is acceptable as the changes increase the product not the diluent.